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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/835,995 | 04/17/2001 | Charlotte Soderberg | 00146regUS | 8766 |

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| EXAMINER |
|---|
| LANDSMAN, ROBERT S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 17 |

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/835,995 | SODERBERG ET AL. | |
| | Examiner | Art Unit | |
| | Robert Landsman | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33 and 35-87* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 36-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-33,35 and 80-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

***1. Formal Matters***

A. Amendment A, filed 5/14/03, has been entered into the record.

B. Claims 1-79 were pending in the application. Applicants cancelled claim 34 and added new claims 80-87. Claims 1-29 and 36-79 were withdrawn as being drawn to a non-elected invention. Therefore, claims 30-33, 35 and 80-87 are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

***2. Information Disclosure Statement***

A. A copy of the PTO-1449 filed 7/5/01 has been received and considered.

B. Reference AM on the Form PTO-1449 filed 7/5/01 has been lined through since there is no publication date cited in the reference.

***3. Claim Objections***

A. The objection of claims 30-33 and 35 has been withdrawn since the claims no longer depend from a non-elected claim.

***4. Claim Rejections - 35 USC § 101***

A. Claims 30-33 and 35 remain rejected and new claims 80-87 are also rejected under 35 USC 101 for the reasons already of record on pages 3-5 of the Office Action dated 11/14/02. Applicants argue that the claimed invention has real-world uses since it can be used to identify ligands and protein binding partners, or to generate antibodies which can be used, for example, to identify specific tissue types and that Applicants only need to show "reasonable probability" that the claimed invention has utility. Applicants argue that one of ordinary skill in the art would believe the asserted utility and that all asserted utilities are based on sound logic and that the Office provides no evidence that the logic is seriously flawed. Furthermore, they argue that the references cited by the Examiner teach that it may be difficult to make predictions about protein function with certainty, but this is not the 'countervailing evidence." Applicants further argue that GPCRs have a well-established utility, especially in the field of therapeutics and that numerous patents involving GPCRs have been issued with no knowledge of natural substrates or specific biological significance is ascribed to the protein.

These arguments have been considered, but are not deemed persuasive. First, the fact that the protein of the present invention can be used to identify ligands and protein binding partners or to generate antibodies is neither specific nor substantial. There are at least hundreds of proteins known in the art which can be used to identify ligands, or binding partners. This characteristic is not specific to the protein of the present invention. Applicants' argument that the claimed receptor is believed to be a G protein-coupled receptor and that hundreds of therapeutic agents targeting these 7 transmembrane receptors have been introduced into the market is not predictive of a use. Applicants have not identified any specific therapeutics which can modulate the protein of the present invention in order to treat any diseases. In addition, the use of a protein to create antibodies is neither specific, nor substantial since, again, any protein can be used to produce an antibody. Applicants have not taught that these antibodies will have a specific and substantial function. The use of antibodies to identify tissue types is, itself, not specific. For example, Applicants have not demonstrated that the tissue distribution of the protein of the invention is unique and that this distribution would be indicative of a specific disease state, nor, more generally, have they taught what specific information this tissue-typing provides that can be attributed to this specific protein. This further characterization is part of the act of invention and, until it has been undertaken, Applicants' claimed invention is incomplete. Again, "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

Regarding the cited references the Examiner agrees that, at most, there is conflicting evidence that function can be predicted from structure. Regarding the issuing of numerous U.S. Patents, all U.S. Patents are presumed valid.

***5. Claim Rejections - 35 USC § 112, first paragraph - enablement***

A. Claims 30-33 and 35 remain rejected and claims 80-87 are also rejected under 35 USC 112 for the reasons already of record on page 5 of the Office Action dated 11/14/02 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. Furthermore, even if the claims possessed utility under 35 USC 101, claims 32, 33, 80-82 and 85-87 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while then being enabling for the protein of SEQ ID NO:2, does not reasonably provide enablement for proteins which are at least 60% - 95% identical to SEQ ID NO:2, or which hybridize to SEQ ID NO:1. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all proteins which are "**at least 60% identical**" to SEQ ID NO:2, or those which "**hybridize**" under stringent conditions to SEQ ID NO:1. Nucleic acid molecules which "hybridize" to SEQ ID NO:1 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO:1. Similarly, proteins which are "at least 60% identical" to the protein of SEQ ID NO:2 would encode for a protein with one or more amino acid substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:2.

Applicants provide no guidance or working examples of nucleic acid molecules which hybridize to SEQ ID NO:1, or of proteins which are at least 60% identical to SEQ ID NO:2, nor do they provide a *function* of these nucleic acid molecules, or of the proteins which they encode. Applicants have provided no guidance as to what critical residues are required to maintain the functional characteristics of the protein of SEQ ID NO:2. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional sodium channel protein which is less than 100% identical to that of SEQ ID NO:2.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all nucleic acids which hybridize to SEQ ID NO:1 and with regard to all proteins which are at least 60% identical to SEQ ID NO:2. There is also a lack of guidance and working examples of these nucleic acid molecules and proteins as well as which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional protein other that that of SEQ ID NO:2 leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

C. The rejection of claim 35 under 35 USC 112, first paragraph, regarding "allelic variant" has been withdrawn in view of Applicants removal of this term from the claims.

***6. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. The rejection of claim 35 under 35 USC 112, first paragraph, regarding "allelic variant" has been withdrawn in view of Applicants removal of this term from the claims.

B. Claims 32, 33, 80-82 and 85-87 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Nucleic acid molecules which "**hybridize**" to those polynucleotides encoding SEQ ID NO:1 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotides. Similarly, proteins which are "**at least 60% - 95% identical**" to the proteins of SEQ ID NO:2, would have one or more amino acid substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:2.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:1 and 2, or molecules which hybridize to SEQ ID NO:1 (which could be at least thousands of molecules) alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

***7. Claim Rejections - 35 USC § 112, second paragraph***

A. The rejection of claim 32 under 35 USC 112, second paragraph, regarding the term "homologous" has been withdrawn since Applicants have recited a specific % homology.

B. Claims 85-87 are vague and indefinite since the claim recites "stringent conditions." It is not known what these conditions are. Nucleic acid molecules which hybridize under conditions of "low" stringency would not necessarily hybridize under conditions of "high" stringency. Furthermore, not all conditions of "high" or "low" stringency, for example, are the same. Therefore, it is required that Applicants amend the claims to recite the exact hybridization conditions without using indefinite phrases such as "*for example*" **without adding new matter**.

***8. Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 30, 35, 83 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonaldo et al. (cited on the Form PTO-892 of the Office Action mailed 11/14.02. The claims recite a polypeptide comprising an epitope fragment of at least 5 amino acids of SEQ ID NO:2. Bonaldo et al. teach a nucleic acid encoding 193 residues of SEQ ID NO:2 of the present invention (see Sequence Comparison of Office Action dated 11/24/02). Though Bonaldo et al. do not specifically teach the protein or composition, the artisan, given the nucleic acid sequence of Bonaldo, which encodes a protein which is 193 residues of SEQ ID NO:2, would immediately envision the protein as well as a composition, such as the protein in water or buffer.

***9. Conclusion***

A. No claim is allowable.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 25, 2003

ROBERT LANDSMAN
PATENT EXAMINER